The following corrections or additions to the January 2004 list were published in the Federal Register in January 2004.

New Approvals

ANADA Number: 200-367

Pioneer Product:	140-897
Trade Name:	Synovex® T120; Synovex® T80; Synovex® T40
Ingredients:	Trenbolone acetate, estradiol
Sponsor:	Fort Dodge Animal Health, Division of Wyeth
Approval Date:	November 18, 2003
Status:	Over-the-counter
Route:	Subcutaneous (ear)
Species:	Cattle: steers fed in confinement and pasture cattle (slaughter, stocker and feeder steers and heifers)
Drug Form:	Implant
Concentration:	Each pellet contains 20 milligrams trenbolone acetate and 4 mg estradiol. Synovex® T120 contains 6 pellets, Synovex® T80 contains 4 pellets, and Synovex® T40 contains 2 pellets.
Indications:	For increased rate of weight gain and improved feed efficiency when used at 120 or 80 milligrams trenbolone acetate and 24 or 16 milligrams estradiol, respectively. For increased rate of weight gain when used at 40 milligrams trenbolone acetate and 8 milligrams estradiol
Tolerance:	21CFR 556.739 Trenbolone: A tolerance for trenbolone residues in uncooked edible tissues of cattle is not needed. 21CFR 556.240 Estradiol: No residues of estradiol, resulting from the use of estradiol or any of the related esters, are permitted in excess of the following increments above the concentrations of estradiol naturally presented in untreated cattle: 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver.
Withdrawal:	Not required.

21CFR 522.2477

NADA Number: 141-178

Trade Name:	Navigator®
Ingredients:	Nitazoxanide
Sponsor:	IDEXX Pharmaceuticals, Inc.
Approval Date:	November 18, 2003
Status:	Prescription only
Route:	Oral
Species:	Horses
Drug Form:	Paste
Concentration:	27.2 grams per syringe
Indications:	For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*.

Patent number:	Expiration date:
5,578,621	September 8, 2014
5,935,591	January 15, 2018
5,968,961	May 7, 2017
6,117,894	May 7, 2017

Exclusivity: 5 years

21CFR 520.1498

NADA Number: 141-187

Trade Name:	Crystalyx® Iono-Lyx®
Ingredients:	Lasalocid
Sponsor:	Ridley Block Operations Inc.
Approval Date:	December 12, 2003
Status:	Over-the-counter
Route:	Oral
Species:	Cattle, pasture (slaughter, stocker, feeder, and dairy and beef replacement heifers)
Drug Form:	Type A medicated article to make Type C medicated feed block
Concentration:	300 grams of lasalocid sodium per ton in the Type C medicated feed
Indications:	For increased rate of weight gain.
Tolerance:	21CFR 556.347 Lasalocid: The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 0.7 part per million.
Withdrawal:	Zero days
Exclusivity:	3 years

21CFR 558.311 & 510.600

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 140-841

This supplemental application provides for topical use of ivermectin to control infections and prevent reinfection with *Oesophagostomum radiatum* and *Dictyocaulus viviparous* for 28 days after treatment, *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment, *C. surnabada* for 14 days after treatment, and *Damalinia bovis* for 56 days after treatment.

Trade Name:	Ivomec® Pour-On for Cattle
Ingredients:	Ivermectin
Sponsor:	Merial Ltd.
Approval Date:	November 24, 2003
Status:	Over-the-counter
Route:	Topical
Species:	Cattle
Drug Form:	Liquid (solution)
Concentration:	5 milligrams per milliliter
Indications:	For the control of infections and protects cattle against reinfection with: *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Cooperia surnabada* for 14 days after treatment and *Damalinia bovis* for 56 days after treatment.
Tolerance:	21CFR 556.344 Ivermectin: A tolerance is established for 22,23-dihydroavermectin B_1a (marke residue) as 100 parts per billion in liver and 10 parts per billion in muscle.
Withdrawal:	48 days. A withdrawal time in milk and pre-ruminating calves have not been established.
Exclusivity:	3 years

21CFR 524.1193

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 140-890

This supplemental application provides for revision of the susceptibility information for food-animal pathogens listed in the clinical microbiology section of the labeling.

Trade Name: Excenel® RTU
Ingredients: Ceftiofur Hydrochloride
Sponsor: Pharmacia & Upjohn Co.
Approval Date: December 12, 2003

Addition of Sponsor

Ridley Block Operations Inc.
424 North Riverfront Dr.
P.O. Box 8500
Mankato, MN 56002-8500
Labeler code: 068287

Removal of Patent Numbers

Patent Number: 4,665,100
Expiration Date: May 12, 2004
NADA Numbers: 030-330, 041-275, 091-749, 094-402, 097-615, 097-981, 098-156, 098-639, 099-561, 101-906, 107-002, 107-957, 108-484, 109-816, 111-069, 120-614, 122-522, 124-391, 127-506, 127-507, 127-826, 128-255, 128-411, 128-835, 129-159, 129-161, 130-465, 131-956, 131-958, 138-342, 138-453, 138-454, 139-301, 139-601, 140-681, 140-820

Patent number: 4,764,534
Expiration Date: August 16, 2005
NADA Numbers: 092-482, 092-522, 109-471, 118-509, 119-253, 124-309, 125-476, 140-852, 140-865

Patent Number: 4,797,275
Expiration Date: January 10, 2006
NADA Numbers: 135-468, 138-952, 140-926, 140-942, 140-947, 141-113

Amendment to the Federal Food, Drug, and Cosmetic Act

Animal Drug User Fee Act of 2003; Interim Procedures

The Food and Drug Administration (FDA) is announcing interim procedures relating to the Animal Drug User Fee Act (ADUFA) of 2003, which was signed by the President on November 18, 2003. This act amends the Federal Food, Drug, and Cosmetic Act, and authorizes FDA to collect four types of user fees: Application fees, establishment fees, product fees, and sponsor fees. Before FDA can begin collecting these fees, enabling appropriations must be enacted. Until further notice, such fees should not be submitted to FDA. However, sponsors should continue to submit new animal drug applications as in the past until additional direction is provided. Certain types of applications submitted on or after September 1, 2003, will be subject to fees, but an invoice for those fees will not be issued until after enabling appropriations are enacted. FDA will publish another Federal Register notice specifying fee amounts and procedures for submitting payments.

Visit the FDA Web site that provides further information on ADUFA at: http://www.fda.gov/oc/adufa.